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| 10/598,334      | 08/24/2006  | Leon Thomas Lee Marsh | 78104113/N19108     | 2747             |

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| EXAMINER |
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DOUGHERTY, SEAN PATRICK

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| ART UNIT | PAPER NUMBER |
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3736

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

08/05/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-ip@dewittross.com

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/598,334 | <b>Applicant(s)</b><br>MARSH, LEON THOMAS LEE |  |
|                              | <b>Examiner</b><br>SEAN P. DOUGHERTY | <b>Art Unit</b><br>3736                       |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is the second Office action based on the 10/598334 application filed 10/598334. Claims 1-15 and 18 are currently pending and have been fully considered below.

### ***Response to Amendment***

The amendment(s) filed 04/29/2009 by Applicant have been considered by Examiner. Examiner acknowledges amended claim(s) 4-10 and 12-14, new claim(s) 18 and cancelled claim(s) 16 and 17. The 112 first paragraph rejection regarding the “computer code” and “computer program” is maintained by Examiner. All other previous rejection(s) of claim(s) are withdrawn. The following new ground(s) of rejection(s) is/are set forth below:

### ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-15 and 18 are rejected as the adequacy of the disclosure to enable a person of ordinary skill in the art to make and use the claimed invention is questioned by Examiner. Any person skilled in the art could not make and use the invention without undue experimentation. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

The "formula" at page 7, lines 15-18 of Applicant's specification is called into question. Specifically, the formula requires a "factor of ambient compensation" and the specification establishes that the factor "may be between 0.1 and 0.23 degrees centigrade and refers to the increase in the subject's core body temperature". Such number appears to simply be a mythical number because it is beyond routine experimentation for one of ordinary skill in the art to determine how the factor is chosen. The logic behind exactly how the number is chosen is non-existent in the specification. The specification simply suggests that a number between 0.1 and 0.23 may be chosen and that it refers to an increase in temperature. Without explanation as to regarding *how* the number is chosen, *what factors* lead to such decision and *how* the factor refers to the increase in the subject's core body temperature, a skilled artisan would be

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required to perform undo experimentation to correctly or most accurately pick a number between 0.1 and 0.23. Factors that may influence the chosen factor of ambient compensation are not explained, such missing factors may include the user's height, weight, sex, initial hydration, etc. It not enabled how the factor works or how it is chosen, therefore, it is beyond routine experimentation of one of ordinary skill in the art and a skilled artisan would not be able to make use of the invention.

Claim 18 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. "A computer program" and "computer code" is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant was not in possession of the "computer program" or "computer code" at the original filing date of the application. The disclosure fails the mention the term "computer code" of even a "computer program". It is unknown what the code is of, how the code functions, how the code is drafted or what the code does in regard to measuring hydration. Any person skilled in the art could not make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite as the claim is incomplete. Claim 1 recites the limitation where a hydration level is calculated "in dependence on changes in the measured core body temperature", however, the Applicant's specification establishes that the hydration level is calculated in dependence of other factors including a "subject's weight" and a "factor of ambient compensation" as established bridging pages 7 and 8 and in the "formula" at page 7, lines 15-18 of Applicant's specification. One having an ordinary skill in the art at would not know what is included with the claims and what is excluded by the claims, when the claims are read in light of the specification because essential elements of calculating hydration level have not be included in claim 1. A skilled artisan would find the bounds of the claim indefinite as it is not known if the limitations "subject's weight" and a "factor of ambient compensation" are included with claim 1 to provide a hydration level when the claim is read in light of the specification, because such limitations are required for calculating the hydration level. Therefore, claim 1, and dependant claims 2-9 and 11-13 are considered indefinite and incomplete.

Claim(s) 14, 15 and 18 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 14 and 18, the claims recite "multiplying by the subject's weight" and "dividing by a factor of ambient

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compensation". It is unclear what is multiplied by the subject's weight and what is being divided by a factor of ambient compensation.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 9-14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,138,079 to Putnam (hereinafter "Putnam") in view of US 6,540,686 to Heikkilä et al. (hereinafter "Heikkilä").

Putnam discloses a method of measuring hydration of a subject ("DEVICE FOR CALCULATING FLUID LOSS FROM A BODY DURING EXERCISE" see Title) in a hydration monitor (hydration calculation device, 10) comprising the steps of using the formula best seen at col. 6, ll. 10-11 and determining the rate of total heat lost by the body ("THLr" col. 5, ll. 26-29) in kilocalories using a MET Range seen at the table at the

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top of col. 5, multiplying by the subject's weight (where W is the subject's weight, see col. 5, ll. 26) and dividing by a factor of ambient compensation (where 1450 is the factor of ambient compensation, see col. 6, ll. 10-11 and 19-29) which is performed by a processor ("processing means" 42). Putman further discloses where the hydration is arranged to operate repeatedly at a predetermined time intervals and where the processor is arranged to generate an alarm upon determination of a hydration level below a predetermined level (col. 2, ll. 59-65, col. 3, ll. 9-27). Putnam does not expressly disclose measuring with a temperature sensor an initial body temperature of a subject, measuring with a temperature sensor a subsequent current core body temperature of a subject and subtracting the initial core body temperature from the subsequent core body temperature as set forth in claims 1 and 14, nor does Putman expressly disclose a memory for storing hydration level and/or core body temperature over time as set forth in claim 9.

Heikkilä et al. is a reference in analogous art that teaches a mathematical model which is based on the physiological facts of the human energy metabolism. The mathematical procedures include arithmetic operations, such as adding, subtracting and multiplying. The level of energy metabolism, i.e. the amount of energy consumed, is given as output variables of the mathematical model. Energy consumption can be determined as energy/time unit, i.e. kcal/min (col. 2, ll. 33-61) and is computed using both a physiological parameter and optional input parameters. The physiological parameter includes weight (col. 3, ll. 9-10) and the optional input parameter includes body temperature (col. 3, ll. 19-21). Specifically, Heikkilä et al. teaches measuring an initial



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core body temperature with a temperature sensor ("body temperature, which can be measured e.g. from the skin by a thermometer" col. 3, ll. 19-21) and a subsequent core body temperature of the user with the temperature sensor and subtracting the initial core body temperature from the subsequent core body temperature as Heikkilaet teaches detecting changes in skin temperature ("rate of change of the heart rate or other such variable measurable from heart beats" col. 3, ll. 4-7) using a processor (col. 4, ll. 23-36). Heikkilaet teaches a memory ("memory" 448) for storing hydration level and/or core body temperature over time,

Examiner notes that the method of Putnam for determining the number of kcal expended, and subsequently a hydration status of a user, is a rough, table form calculation. The method of Heikkilaet achieves the same result of the number of kcal expended by using a real-time, skin temperature measurement. One having an ordinary skill in the art would find the combination of Putnam and Heikkilaet advantageous because the predictable result of determining variables relating to human energy metabolism would ensue (col. 1, ll. 7-9). Examiner notes that such modification would be obvious because it is a more advanced method of determining the number of kcal expended and achieves a specific result based on patient temperature. Rather than simply estimating the energy expenditure with the MET range of Putnam, Heikkilaet provides an improved method using a temperature sensor to achieve the same result (col. 1, ll. 47-48). Therefore, a skilled artisan would have found the combination of Putnam and Heikkilaet obvious.

Regarding claim 11, Putnam in view of Heikkilaet discloses the claimed invention except for where the factor of ambient compensation is between 0.1 and 0.23 and is determined in dependence on the temperature of the environment surrounding the subject. It would have been obvious to one having ordinary skill in the art at the time the invention was made to the factor of ambient compensation of Putnam, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 2-8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,138,079 to Putnam (hereinafter "Putnam") in view of US 6,540,686 to Heikkilaet et al. (hereinafter "Heikkilaet"), as applied to claim 1 and 14 respectively, further in view of US 5,381,796 to Pompei (hereinafter "Pompei").

Putman discloses a remote unit (hydration calculation device, 10) being a medical diagnostic that includes a processor ("processing means" 42) that is arranged to provide an indication of the hydration level via output means (display screen, 22) and Heikkilaet discloses a sensor including a transmitter and a remote unit including a receiver that transmit information wirelessly and communicate (see claim 43). Putman as modified by Heikkilaet does not expressly disclose where the temperature measurements are taken from a subject's tympanic membrane using a thermopile positioned in an earpiece and transmitted from a transmitter comprised with the earpiece to a receiver.

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Pompei is a reference in analogous art that teaches a thermopile (thermopile radiation sensor, 28) positioned in an earpiece (portion, 38) for measuring tympanic temperature (col. 1, ll. 31-40). One having an ordinary skill in the art at the time the invention was made would have found it obvious to modify the method of taking measurements of temperature of Putman to be taken from the tympanic membrane measurement method of Pompei using the earpiece and communicating via a transmitter wirelessly with a receiver, since the predictable result of providing an alternative to traditional sublingual thermometers as taught by Pompei at col. 1, ll. 11-12 would allow for comfortable, accurate and rapid tympanic wireless temperature measurements from a transmitter in the earpiece to a receiver with only moderate training of a user. Therefore, a skilled artisan would have found the combination of Putnam as modified and Pompei obvious.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

### ***Contact Information***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean P. Dougherty/  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736